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MAY 16 2008

Bruce E. Kramer  
Sughrue Mion PLLC  
2100 Pennsylvania Avenue, NW  
Suite 800  
Washington, DC 20037-3213

In re: Patent Term Extension  
Application for  
U.S. Patent No. 5,284,858

Dear Mr. Kramer:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,284,858 for a period of 1252 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7754, or by e-mail at [kathleen.fonda@uspto.gov](mailto:kathleen.fonda@uspto.gov).

Kathleen Kahler Fonda  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Re: AMITIZA® (lubiprostone)  
FDA Docket No.: 2006E-0355

Attention: Beverly Friedman

# UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,284,858  
(45) ISSUED : February 8, 1994  
(75) INVENTOR : Ryuzo Ueno et al.  
(73) PATENT OWNER : Sucampo AG  
(95) PRODUCT : AMITIZA® (lubiprostone)

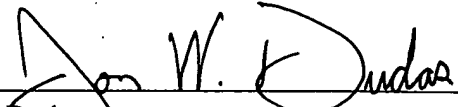
This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,284,858 based upon the regulatory review of the product AMITIZA® (lubiprostone) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1252 days

from February 8, 2011, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 3rd day of April 2008.

  
Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office